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43. The method of claim 42 wherein the aqueous fluid is substantially free of preservatives.--

REMARKS

Applicant submits this Amendment in response to the Office Action dated February 12, 2001.

Independent claims 1, 15, and 19 have been amended to call for an aqueous fluid that consists essentially of water. Thus, the aqueous fluid of these claims is free of topical or ophthalmic medications. Support in the specification for this amendment is found throughout the specification, for example at page 6, lines 30 to 36. Claim 1 has been further amended to delete the term "controllably" as this term is not considered to be necessary to define the invention. Claims 1, 15, and 23 have been amended to substitute the term "moisturize" in place of the term "hydrate", as the term "moisturize" more accurately defines the invention. Claims 15 and 19 have also been amended to delete the term "within about 10 seconds", as this term is considered to be unnecessary to define the invention. Claims 1, 11, 15, 19, and 20 have been amended for clarification as discussed in more detail below. Claims 24 to 27, which depend from independent claims 1, 15, 19, and 23, respectively, have been added. Support for these new claims in the specification is found on page 7, lines 11 to 12. Independent claim 28, and claims 29 to 43 which depend therefrom, have been added. Support for claim 28 is found in the specification on pages 5 and 6, bridging paragraph. Claims 29 to 43 are parallel claims to claims already pending.

REJECTIONS OF THE CLAIMS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claims 1 to 22 as being indefinite under 35 U.S.C. §112, second paragraph. Applicant traverses the rejection of these claims and responds to the rejections as follows.

1. Claim 1 has been amended to delete the term "controllably".

2. As suggested by the Examiner, claim 11 has been amended to delete the first occurrence of the term "has".

3. Applicant respectfully traverses the Examiner's finding that the term "within about 10 seconds" in claims 15 and 19 is indefinite. Applicant submits that it is clear from the specification that this term indicates that the length of time for the administration of the fluid to the eye is about 10 seconds or less. See page 9 of the specification, lines 12 to 16. However, because Applicant believes that this term is not necessary to define the invention, this term has been deleted from the claims.

4. Claim 20 has been amended to call for between 5 and 150 microns, in parallel to what is called for in claim 5. As amended, claim 20 contains a range which encompasses the ranges called for in claims 21 and 22.

5. These claim amendments overcome the rejection of claims 2-14, 16-18, and 20-22, as being indefinite for being dependent on indefinite claims.

Applicant submits that the claims, as amended, are definite within the requirements of 35 U.S.C. §112, second paragraph, and requests the Examiner to withdraw the rejection of these claims on this ground.

REJECTIONS OVER PRIOR ART

1. REJECTION OF CLAIMS UNDER 35 U.S.C. §102(b)

Claims 1-10 and 15-22 have been rejected under 35 U.S.C. §102(b) as being anticipated by Rocca et al, WO 96/00050, in view of Records, "The Tear Film," Chapter 3 of Volume 2 of Biomedical Foundations of Ophthalmology, Ed. William Tasman and Edward Jaeger, Lippincott Publishers. Applicant traverses the rejection of these claims on this ground.

Rocca discloses a device for applying a treatment liquid to the surface of the eye, wherein the treatment liquid is applied in a jet or multiple droplets of 20 micron to 200 micron diameter. See page 8, line 22. Rocca discloses that the device provides for delivering a greater proportion of a treatment liquid so that it will actually make contact with the eye. This leads to less wastage, reduced risk of systemic absorption, and less flooding of the eye which can result in a treatment being wasted. See page 8, lines 29-36. On pages 13 to 14, Rocca illustrates the use of the device of the invention by an example in which pilocarpine, a drug to induce miosis (pupillary contraction) was administered to the surface of the eye.

In contrast to the present application, and to the invention as claimed, Rocca does not disclose a method for moisturizing the eye. Further, Rocca does not disclose or suggest a method for moisturizing the eye in which an aqueous fluid consisting essentially of water is administered to the surface of the eye.

Applicant submits, therefore, that the rejection of these claims as being anticipated by Rocca under 35 U.S.C. §102(b) is overcome and requests that the rejection on this ground be withdrawn.

Further, Applicant submits that the rejected claims (1-10 and 15-22) are not obvious in view of the disclosure of Rocca. Rocca discloses that her invention is useful because it prevents wastage of therapeutic liquids (such as pilocarpine). This is so because if a therapeutic liquid is administered in too large a volume of fluid, it will run out of the eyes and be wasted or may be absorbed systemically.

Rocca does not disclose, as is disclosed in the present application, that administering such a small volume of water is actually beneficial in and of itself in moisturizing the surface of the eye. Nor does Rocca disclose or suggest the present invention, which is superior to present eye-moisturizing methods that over-hydrate the surface of the eye with resultant destruction of the natural composition of the aqueous layer of the tear film. Moreover, Rocca does not disclose any method of treatment of the eye in which a fluid consisting essentially of water is administered to the surface of the eye.

For these reasons, Applicant respectfully submits that the rejection of claims 1-10 and 15-22 over the disclosure of Rocca has been overcome and requests the Examiner to withdraw the rejection of the claims on this ground.

2. REJECTION OF CLAIMS UNDER 35 U.S.C. §103

The Examiner has rejected claims 1 to 23 under 35 U.S.C. §103 as being obvious in view of the combined disclosure of Rocca, WO 96/00050, and Varma, U.S. Patent No. 5,032,392. Applicant traverses the rejection of the claims on this ground.

The disclosure of Rocca is discussed above. As noted, Rocca by itself neither discloses nor suggests the claimed invention. Applicant submits that the disclosure of Varma does not fill

in the gaps left by the disclosure of Rocca and that the combined disclosures of Rocca and Varma do not suggest the claimed invention.

Varma discloses an aqueous ophthalmic solution for the treatment of dryness of the eye. The solution contains Vitamin A in combination with other ingredients, including (1) free radical scavengers such as EDTA or mannitol, (2) an alkali salt, sucrose, or other tonicity maintaining constituents, (3) a buffer, and (4) a surfactant. See, column 3, lines 1-6, 35, and 54, column 4, lines 11-17, and 40-44, and column 5, lines 20-29. Varma does not disclose or suggest an ophthalmic solution for the treatment of dryness of the eyes that consists essentially of water, as is currently claimed in claims 1 to 22.

Moreover, Varma does not disclose nor suggest that the amounts called for in the present claims are useful for treatment of dryness of the eye. Rather, Varma discloses that 2 drops of the solution were placed into the eye. As disclosed in the present application, a drop generally provides about 20 to 25 μl of fluid. See the present specification at page 2, lines 26-28. Therefore, Varma discloses applying between 40 and 50 μl of fluid to the surface of the eye. Such an amount would surely flood the eye, resulting in washing away the normal aqueous layer of the tear film and incomplete moisturizing of the eye for several blink cycles. See the present specification at page 2, line 29, to page 3, line 2.

It is this problem that is addressed and solved by the present invention. The prior art does not disclose, nor does it suggest, that moisturizing of the eye is most effective when performed in accordance with the presently claimed invention. The invention is a significant step forward in therapy for dryness of the eye.

Claims 1 to 22 have been amended to call for a fluid that consists essentially of water. This is not disclosed nor suggested by the prior art, either alone or in combination. Claim 23 has not been amended to call for consisting essentially of water. In view of the preceding remarks, Applicant submits that this claim, also, is patentably distinguishable over the prior art.

Accordingly, Applicant submits that the rejection of the claims for obviousness under 35 U.S.C. 103 has been overcome and requests the Examiner to withdraw the rejection of the claims on this ground.

NEW SET OF CLAIMS

Applicant submits that new claims 28 to 43 are patentable over the prior art which does not disclose or suggest a method for moisturizing the aqueous layer of the tear film of the eye without washing away this layer.

CONCLUSION

Applicant submits that the application, as amended, is in condition for allowance and requests an early notice to that effect.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231, on March 15, 2001.

Dated: 3/15/2001

Howard M. Eisenberg

Appendix - Marked-up copy of the claims

Please amend the claims as follows.

1. (Amended) A method for moisturizing the eye comprising [controllably] administering to the surface of the eye an aqueous fluid consisting essentially of water in an amount that is sufficient to increase the volume of the aqueous layer of the tear film by at least 5% of the volume of the normal aqueous layer and which amount is less than that which causes runoff of the tear film from the eye and permitting the fluid to [hydrate] moisturize the aqueous layer of the tear film.

2. (Amended) The method of claim 1 wherein the amount of the fluid is between 50 and 200% of the volume of the normal aqueous layer of the tear film.

8. (Amended) The method of claim 1 wherein the quantity of the fluid that is administered to the eye surface is less than about 10 μl.

11. (Amended) The method of claim 1 wherein the fluid [has] administered has an osmolarity of less than that of the normal aqueous layer of the tear film.

15. (Amended) A method for moisturizing the surface of the eye comprising administering to said surface of the eye between 0.5 and 20 μl of an aqueous fluid consisting essentially of water [within about 10 seconds] and permitting said fluid to [hydrate] moisturize the aqueous layer of the tear film of said eye.

19. (Amended) A kit for moisturizing the eye comprising a container, a fluid consisting essentially of water within said container, an actuator that delivers between 0.5 and 20 μl of said fluid [within about 10 seconds], and instructions for delivering said dose of fluid to the surface of the eye.

20. (Amended) The kit of claim 19 wherein the actuator delivers the fluid as a mist having an average droplet size between [50] 5 and 150 microns in diameter.

23. (Amended) A method for moisturizing the eye comprising administering to the surface of said eye between 0.5 and 10 μl of an aqueous fluid wherein said fluid is in the form of a mist comprised of droplets having an average size between 5 and 150 microns and wherein the fluid has a pH less than or equal to 7.0 and an osmolarity below that of the normal tear film and permitting said fluid to [rehydrate] moisturize the aqueous portion of the tear film of said eye.

Please add the following claims:

--24. The method of claim 1 wherein the aqueous fluid is substantially free of preservatives.

25. The method of claim 15 wherein the aqueous fluid is substantially free of preservatives.

26. The kit of claim 19 wherein the fluid is substantially free of preservatives.

27. The method of claim 23 wherein the aqueous fluid is substantially free of preservatives.

28. A method for moisturizing the aqueous layer of the tear film on the surface of the eye without washing away said aqueous layer, which method comprises administering to the surface of the eye an aqueous fluid in an amount that is sufficient to increase the volume of the aqueous layer of the tear film by at least 5% of the volume of the normal aqueous layer and which amount is less than that which causes runoff of the tear film from the eye and permitting the fluid to moisturize the aqueous layer of the tear film.

29. The method of claim 28 wherein the amount of the fluid is between 50 and 200% of the volume of the normal aqueous layer of the tear film.

30. The method of claim 28 wherein the fluid is administered in the form of a mist.

31. The method of claim 30 wherein the mist is composed of droplets having an average volume of about 0.1% to 1% of the volume of the normal tear film.

32. The method of claim 30 wherein the mist is composed of droplets having an average size of between about 5 and 150 microns in diameter.

33. The method of claim 32 wherein the average size of the droplets is between 10 and 50 microns in diameter.

34. The method of claim 33 wherein the average size of the droplets is between 15 and 30 microns in diameter.

35. The method of claim 28 wherein the quantity of the fluid that is administered to the eye surface is less than about 10 μl.

36. The method of claim 35 wherein the quantity is between about 0.5 and 6 μl.

37. The method of claim 36 wherein the quantity is between about 2 and 5 μl.

38. The method of claim 28 wherein the fluid has an osmolarity of less than that of the normal aqueous layer of the tear film.

39. The method of claim 38 wherein the osmolarity is less than 311 mOsm.

40. The method of claim 28 wherein the pH of the fluid is less than 7.

41. The method of claim 40 wherein the pH is about 6.5.

42. The method of claim 28 wherein the aqueous fluid consists essentially of water.

43. The method of claim 42 wherein the aqueous fluid is substantially free of preservatives.--